

NOVO NORDISK A S  
Form 6-K  
December 22, 2003

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**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 6-K**

Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934  
19 December 2003

**NOVO NORDISK A/S**

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(Exact name of Registrant as specified in its charter)

**Novo Allé**  
**DK- 2880, Bagsvaerd**  
**Denmark**

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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

Form 20-F  Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If  is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b): 82-\_\_\_\_\_

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

Date: 19 December 2003

NOVO NORDISK A/S

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Lars Rebien Sørensen, President and Chief Executive Officer

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## Stock Exchange Announcement

19 December 2003

### Breakthrough for NovoSeven®: new study shows significant reduction in blood transfusion needed in trauma patients

Novo Nordisk today announced the first results from its phase 2 studies of the safety and efficacy of NovoSeven® in trauma patients. The study shows that patients receiving treatment with NovoSeven® needed significantly less red blood cell transfusion than patients receiving conventional treatment.

Furthermore, results indicate that patients treated with NovoSeven® had fewer complications and spent less time in intensive care units than patients receiving conventional treatment and, further, that overall mortality was lower in the group treated with NovoSeven®. However, as the study was not designed to show differences in these parameters, these findings need to be investigated further in a subsequent study.

Equally important, in terms of safety, the study revealed no difference between the two treatment groups in the number or types of serious adverse events, including thromboembolic events.

Lars Rebien Sørensen, president and chief executive officer of Novo Nordisk, said: "The proof of concept for the use of NovoSeven® is a major breakthrough in the treatment of patients with trauma and one of the most important events in Novo Nordisk's R&D pipeline in recent years."

The trauma study involved 280 patients in five continents, with critical bleeding related to either blunt or penetrating trauma. Patients that had been hospitalised with life-threatening bleeding, and who had already received transfusion of approximately 8 units of blood, were randomised to receive either NovoSeven® or placebo, in addition to conventional treatment.

In the patients whose bleeding was caused by a blunt trauma, for example victims of traffic accidents, the effect of NovoSeven® in reducing bleeding was statistically significant. In patients whose bleeding was caused by penetrating trauma, for example gunshots, there was a strong trend towards reduction of bleeding. In most countries blunt trauma is responsible for 75-95% of the total number of traumatic injuries.

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24256790

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**UPDATE ON OTHER NOVOSEVEN® STUDIES**

Novo Nordisk has also finalised a study of the effect of NovoSeven® on bleeding in patients undergoing stem cell transplantation. In this study 100 patients suffering from moderate to severe bleeding episodes were treated with various doses of NovoSeven® or placebo, in addition to standard treatment. Although a statistically significant dose-response was not seen, results indicated a clinical effect at a relevant dose. The effect of NovoSeven® for patients undergoing stem cell transplantation will be investigated further in an already ongoing study.

As announced in Novo Nordisk's financial statement for the first nine months of 2003 on 29 October 2003, Novo Nordisk also expects to be able to report the conclusions from a study of the use of NovoSeven® in connection with liver transplantation in the first quarter of 2004.

The above scientific results do not change Novo Nordisk's expectations for the financial results for 2003.

**CONFERENCE CALL**

At 16.00 CET today, corresponding to 15.00 UK time and 10.00 am New York time, a brief conference call about the findings of the study will be held. The number of the conference call is +44 207 162 0180 / +1 334 323 6203 and the password is Novo Nordisk. If you have any problem accessing the conference please call Novo Nordisk Investor Relations Coordinator Kazuko Kjeldsen at +45 4442 6035 or +45 3079 6035. Investors will also be able to listen in via a link on [www.novonordisk.com](http://www.novonordisk.com), which can be found under Investors Conference call. Presentation material for the conference call will be made available immediately before the conference on the same page.

**ABOUT TRAUMA**

Serious bleeding is the leading cause of death in traumatic injury related among others to traffic accidents, falls and use of weapons. Approximately 1.5 million people experience a major traumatic event per year in the Western world, and approximately 20% of those need blood transfusion.

In general traumatic injuries can be classified in one of two broad categories according to the injury, namely blunt and penetrating trauma. In the United States the distribution between the two major trauma categories is around 80% being blunt trauma and around 20% being penetrating trauma. Blunt trauma refers to injuries resulting from non-penetrating forces such as traffic accidents or falls. Penetrating injuries result from a piercing of the skin and damage to the deeper tissues or organs of the body. Penetrating injuries typically result from gunshot wounds or stabbing.

Usually a combination of surgical management, non-operative management and intravascular interventions is used in the treatment of trauma. Most patients with severe trauma experience acute haemorrhage. The significant reduction in intravascular blood volume resulting from severe trauma can lead to clinical shock and often cause death.

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However, transfusions are associated with increased mortality and morbidity. Although blood transfusion is a crucial component in the management of trauma patients, recent studies have shown that infection and mortality rates in patients who receive blood transfusion are higher compared to those who do not. Reduction in blood loss, and a reduction in the level of blood transfusion, is therefore an increasingly important management objective.

### **ABOUT NOVOSEVEN®**

NovoSeven® is a recombinant haemostatic agent (recombinant activated factor VII). The product is currently registered for treatment of bleeding episodes in haemophilia patients with congenital or acquired inhibitors against the clotting factors VIII or IX. Its unique mechanism of action induces haemostasis independently of FVIII and FIX. By stimulating a burst of thrombin production on the surface of activated platelets, rFVIIa is able to accelerate and strengthen the body's own clotting process. Factor Xa, in complex with other factors, then converts prothrombin to thrombin, which leads to the formation of a haemostatic plug by converting fibrinogen to fibrin and thereby inducing local haemostasis.

### **FORWARD-LOOKING STATEMENT**

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, Novo Nordisk's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the US Securities and Exchange Commission (SEC) including the company's Form 20-F, which was filed on 27 March 2003. Please also refer to the section "Financial Risk Factors" in the Annual Financial Report 2002. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.

*Novo Nordisk is a focused healthcare company. With the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems, Novo Nordisk is a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs approximately 18,700 people in 68 countries and markets its products in 179 countries. Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange under the symbol NVO. For further company information visit [www.novonordisk.com](http://www.novonordisk.com)*

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